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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,123	10/20/2000	Michael C. Barney	661005.90268	7800

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/693,123

Applicant(s)

BARNEY ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The receipt is acknowledged if applicants' amendment, filed 01/26/2004.

Claims 1-4 are included in the prosecution.

#### ***Claim Rejections - 35 USC § 103:***

1. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,548,552 ('552) in view of US 6,313,178 ('178).

US '552 teaches an absorbent article having additives in a sufficient amount that reduce the toxic shock syndrome toxin production (abstract). The additives are applied to the surface of the absorbent article then dried (col.3, lines 11-20). The absorbent article can be any absorbent article where reduction in toxic shock syndrome toxin production might be beneficial (col.9, lines 50-51).

US '552 does not teach the use of hexahydrolupulone or tetrahydroisohumulone in particular to treat toxic shock syndrome.

US '178 teaches a composition and method for inhibiting the *Staphylococcus aureus* growth. The method comprises contacting the bacteria with an effective amount of hexahydrolupulone (hexahydro-beta acid) or tetrahydroisohumulone (tetrahydroiso-alpha acid). The composition is formulated in an aqueous base water, alcohol, propylene glycol or glycerin. The composition is suitable for topical administration to the

Art Unit: 1615

epidermis (abstract; col.1, lines 30-35; col.2, lines 1-57; col.3, lines 57-62; col.4, lines 63-67; col.5, lines 42, 54-57; col.7, lines 25-29). The hexahydrolupulone and tetrahydroisohumulone are particularly effective against gram-positive bacteria such as *Staphylococcus aureus* (col.2, lines 10-15).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a dry absorbent article that has additives to treat toxic shock syndrome applied to its surface as disclosed by US '552, and replace the additives that treat toxic shock syndrome by hexahydrolupulone or tetrahydroisohumulone as disclosed by US '178, motivated by the teaching of US '178 that hexahydrolupulone or tetrahydroisohumulone are particularly effective against gram positive bacteria such as *Staphylococcus aureus*, with reasonable expectation of having a dry absorbent article with hexahydrolupulone or tetrahydroisohumulone on its surface to inhibit the growth of *Staphylococcus aureus* infection, and consequently, controlling toxic shock syndrome with success.

### **Response to Arguments**

2. Applicant's arguments filed 01/26/2004 have been fully considered but they are not persuasive.

Applicants traverse the rejection of claims 1-4 under U.S.C. 103 (a) over US '552 in view of US '178 by arguing that the non of the references teaches the use of the tetrahydroiso-alpha acids or hexahydro-beta acids at the recited concentration levels of the amended claims. Applicants admit that US '178 teaches such compounds, but

Art Unit: 1615

argue that the reference does not teach the claimed concentration particularly in the acidic environment of the liquid, i.e. urine, and applicants presented data on the activity of the compounds in acidic environments. Applicants submit that all the features of the amended claims are not shown or suggested in US '552 and US '178.

In response to the above argument, the examiner position is that the only difference between the teaching of the prior art and the present invention is the claimed amount, and it is within the skill in the art with routine experimentation to optimize the amount of tetrahydroiso-alpha acids or hexahydro-beta acids disclosed by the prior art to inhibit the growth of *Staphylococcus aureus*.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the acidic environment) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In any event, the prior art teaches the inhibition of organisms in the vagina, and the vaginal environment is also acidic, see US 6,706,276.

In response to applicant's argument that there is no suggestion in US '552 or US '178 for all the features of the amended claims, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5

Art Unit: 1615

USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a dry absorbent article that has additives to treat toxic shock syndrome applied to its surface as disclosed by US '552, and replace the additives that treat toxic shock syndrome by hexahydrolupulone or tetrahydroisohumulone as disclosed by US '178, motivated by the teaching of US '178 that hexahydrolupulone or tetrahydroisohumulone are particularly effective against gram positive bacteria such as *Staphylococcus aureus*, with reasonable expectation of having a dry absorbent article with hexahydrolupulone or tetrahydroisohumulone on its surface to inhibit the growth of *Staphylococcus aureus* infection, and consequently, controlling toxic shock syndrome with success.

### ***Conclusion***

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1615


the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

  
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